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Lloyd Bolling
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Lloyd,

Enclosed are a few comments on the official draft copy of the Part 35 revision.

It is my opinion that the proposed changes include many items that should be incorporated in the regulations and not in license conditions and guides; however, some questions remain.

If I can be of any further assistance, do not hesitate to contact me.

Sincerely,

Mary L. Blazek
Radiation Specialist
Radiation Control Section

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Enclosures

cc: Charles Hardin, Exec. Secretary, Conference of Radiation Control Program Directors
Diane Tefft, Manager, Radiological Health Program, New Hampshire
Kirksey Whatley, Section Chief, Radioactive Materials Licensing, Alabama

1. Page 7 Revision of Regulatory Guide 10.8 for Medical Programs

   The proposed guide appears to address the intent of many of the previously submitted comments, i.e., guidance and training for licensees. In the event, however, that a licensee choses to use an alternative, but equivalent procedure than outlined, it should be documented in the license application. A licensee proposing equivalent procedures may require a pre-licensing or timely post-licensing inspection with emphasis on procedures. It has been our experience that a licensee's perception of "equivalent" is not always acceptable.

2. Page 13 of Enclosure 1, Supplementary Information

   Although post-licensing visits are more acceptable than pre-licensing visits, I still question what the definition of "within a short time after operations" will be.

3. Page 19 of Enclosure 1, Release of Patients (35.75)

   The change from activity to exposure rate is certainly acceptable; however, a requirement for patient instruction appears appropriate for a 5 mr/hr at one meter exposure rate limit. The basis for my concern is the ALARA concept for the spouse/bedmate/children of the patient.

4. Page 39 of Enclosure 1 § 35.17 Amendments

   "A licensee shall apply for and must receive a license amendment (f) before making any changes in the licensed program which could result in a reduction of radiation safety."

   If this question is to be left up to the licensee, some guidance by way of examples might be added to Reg. Guide 10.8.

Mary L. Blazek
Oregon State Health Division
6/4/82

The staff proposes to simplify the licensing process for medical licensees by transferring all requirements for human uses of byproduct material from all sources to 10 CFR Part 35. The regulations would become the sole source of requirements for human use and would serve to regulate the daily uses of radioisotopes at medical facilities. The revised regulations would give licensees and NRC's licensing and inspection personnel a clear and consolidated basis for licensing, operation and inspection activities.

In conjunction with this effort, the staff is revising Regulatory Guide 10.8 for medical programs. The proposed guide will contain at least one procedure acceptable to the Commission for meeting each of the requirements in the proposed regulations for human use. Licensees will thus always have access to a suitable practice for using byproduct material in compliance with the regulations. Those licensees who wish to use alternative, but equivalent, procedures may do so at their discretion.

NRC further proposes to simplify the current review process by eliminating the requirement that applicants submit to NRC for review detailed procedures describing how they intend to meet requirements in the regulations. Licensees will still be required by the regulations, however, to write and establish these procedures, and produce copies for NRC inspections. A new application, NRC 313MH, will be published in the Federal Register

used to meet them. A license amendment would still be required for substantial changes in the type of medical use, or any change in radiological personnel. Overall, the number of amendment requests is expected to substantially decrease as a result of this simplification.

Because lengthy procedural descriptions are presently affixed to licenses as conditions of use, licenses can be 50 pages or more in length. Under the proposed approach, the licensee would operate the facility according to the requirements for human use in the regulations, using the written procedures supplied with the application. The requirements for use are essentially unchanged under this scheme, but the volume of paperwork transferred between NRC and its medical licensees and the volume of the license itself are greatly reduced.

The majority of facilities affected by the revised regulations have already been reviewed and licensed under the present labor intensive process. Last year, NRC received only 73 applications for new medical licenses. There are currently 2,631 established specific licensees. To assure in-depth evaluation for new applicants under the proposed regulations, NRC anticipates conducting post-licensing visits of medical applicants within a short time after operations, have commensed, with the exception of those requesting only the group of uses involving the smallest quantities of radioisotopes.

To summarize, placing all human use requirements in the regulations and eliminating submittal of procedural descriptions would expedite the licensing review process. NRC estimates that eliminating review of procedures would decrease the necessary review time by about 50 percent. Further, the proposed simplifications would eliminate the two major

licensees to use syringe shields to avoid unnecessary exposure of the hands during injection.

Vial Shields (§35.61) - This new requirement would represent an extension of the protection afforded by syringe shields. Shielding the vials from which radiopharmaceuticals are drawn prevents unnecessary exposure of the hands. Vial shields are already in widespread use for this purpose.

Release of Patients (§35.75) - This section changes the patient release criterion from 30 millicuries of radiopharmaceutical activity to an exposure rate of 5 milliroentgens per hour at a distance of one meter from the patient. The scope of this limitation is expanded to include patients with permanent implants.

Mobile Service (§35.80) - This section contains technical requirements that are unique to mobile services.

Exemption for Tc-99m Pentatate Sodium Aerosol (§35.200(c)) - The current Part 35 requires certain licensees using byproduct material for clinical procedures other than those specified by the manufacturer's product labeling, to comply with the product labeling regarding chemical and physical form; route of administration; and dosage range. The proposed Part 35 retains the requirement but provides an exemption for technetium 99m pentatate sodium when used as an aerosol for lung function studies in a closed, shielded system. An identical exemption from the requirement was published as a proposed rule on April 13, 1982, (47 FR 15798), as a result of a petition filed by Dr. George V. Taplin (Docket No. PRM-35-1).

applicant shall mail the completed application form to U.S. Nuclear Regulatory Commission, Region III, Radioisotopes Licensing Section, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

§35.17 Amendments.

A licensee shall apply for and must receive a license amendment:

(a) Before any human use of byproduct material not permitted by the license issued under this part;

(b) Before the licensee permits a physician, other than a visiting physician described in §35.34, to work as an authorized user under the license;

(c) Before the licensee permits an individual not listed on the license to perform the duties of the radiation safety officer;

(d) Before receiving byproduct material in excess of the amount authorized on the license;

(e) Before supplying mobile service to a location not identified on the license; and

(f) Before making any changes in the licensed program which could result in a reduction of radiation safety.

§35.18 Notifications.

The licensee shall notify the Commission in writing on form NRC-313MH within thirty days when an authorized user or radiation safety officer permanently discontinues performance of duties under the license. The licensee shall mail the form to the appropriate address identified in §35.16.